NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

MEMO

To: Department of Health & Senior Services' Research Investigators

From: Matt Weinberg, M.B.
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Office of the Commissioner

Date: 11 July 2006

Subject: Federal Certificate of Confidentiality [HREP-GUI-001-v1]

This Memorandum provides background and guidance on the privacy protections afforded research subjects participating in research covered by a Federal Certificate of Confidentiality ("Certificate"). [Direct language from Federal statutes and regulations are italicized. For a Certificate of Confidentiality *Frequently Asked Questions* webpage hosted by the National Institutes of Health (NIH), go to http://grants.nih.gov/grants/policy/coc/faqs.htm. To obtain a Certificate application and instructions go to http://grants.nih.gov/grants/policy/coc/contacts.htm.

A. BACKGROUND

The NIH are authorized by the Public Health Service Act to issue Certificates to research projects regardless of funding source. Certificates serve to protect research subjects' identifying information by authorizing *persons engaged in biomedical, behavioral, clinical, or other research…to protect the privacy of individuals who are…participating in… such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals* (42 U.S.C. 241(d)). Participation in research comes about when investigators i) intervene with research subjects, ii) interact with research subjects or iii) use or maintain research subjects' identifying information (45 CFR 46.102(f)). Identifying information is defined as *the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject* (42 CFR 2a(2)(g)).

The privacy *protection afforded by a Certificate is permanent with respect to subjects who participated in the research during any time the authorization was in effect* (42 CFR 2a(8)(c)). However, this authorization does not extend to disclosures that are i) consented to by research subjects or their guardians, ii) required by the Federal Food, Drug and Cosmetic Act or regulations promulgated thereunder or iii) required by the U.S. Department of Health & Human Services (DHHS) for an audit, evaluation or investigation of DHHS-funded research (42 CFR 2a(4)(j)(3)). In addition to a Certificate's privacy protections, the Federal regulations for the protection of research subjects also afford privacy protections, as principal investigators are required to provide an assurance on the Certificate's application that they *will comply with all the requirements of 45 CFR Part 46* when conducting DHHS-funded research (42 CFR 2a(4)(g)(1)). Principal investigators whose research is not DHHS-funded must provide an assurance on the Certificate's application that they will comply with the same informed consent requirements as DHHS-funded research (42 CFR 2a(4)(g)(2)).

It is important to note that Certificates do not prohibit the voluntary disclosure of research subjects' identifying information; they only prohibit compulsory disclosures of identifying information (42 CFR 2a(4)(j)(4) and 42 CFR 2a(7)(c)). A compulsory disclosure is a statutory, regulatory or common law requirement to notify a specified authority of, for example, a communicable disease diagnosis, child abuse, elder neglect, or threats of harm to self or others. Specified authorities include local police, "child protective services", "adult protective services", et cetera. In contrast, a voluntary disclosure is an investigator's personal decision to report, for example, child abuse to the specified authority even though the Certificate-granted authorization absolved the investigator from this compulsory disclosure requirement. Absolution from this requirement means investigators are immune from any consequence arising from their decision not to report child abuse, et cetera. An investigator's voluntary disclosure

of research subjects' identifying information is permissible only if the intention to make such a disclosure is explicitly stated in the Institutional Review Board (IRB)-approved informed consent document.

The following delineates the primary ethical obligations and regulatory requirements imposed upon investigators engaged in Certificate-protected research:

I. The Public Health Service Act at 42 U.S.C. 241(d) and Federal regulations at 42 CFR 2a et seq authorizes investigators to withhold research subjects' identifying information.

II. The Federal regulations at 42 CFR 2a(4)(i), 42 CFR 2a(4)(g), 45 CFR 46.111(a)(7), and the Certificate application as signed by the principal investigator and institutional official, require investigators to withhold research subjects' identifying information.

III. The ethical principles set forth in The Belmont Report (Respect for Persons, Beneficence and Justice) and the Federal regulations at 45 CFR 46.116(a)(2) and 45 CFR 46.116(a)(5), require investigators to comply with the terms of the IRB-approved informed consent document.

IV. The Department's Federalwide Assurance (FWA-4020) with the U.S. Department of Health & Human Services and Federal regulations at 45 CFR 46.103(b)(1), require and obligate investigators to honor the privacy commitments made during the consent process.

V. The Certificate application as signed by the principal investigator and institutional official, and the Federal regulations at 45 CFR 46.116(a)(2), 45 CFR 46.116(a)(5) and 45 CFR 46.111(a)(7), require principal investigators to explicitly state in the informed consent document any circumstances under which a research subject's identifying information will be voluntarily disclosed, if any.

B. GUIDANCE

I. The Department's Human Research Ethics Program (HREP) strongly encourages investigators to obtain Certificates for all human subjects research on involving sensitive information that could harm research subjects' financial standing, employability, insurability, reputation, et cetera. Certificates are particularly appropriate for human subjects research on communicable diseases, birth defects, sexual preferences, drug use, mental health or genetic predispositions.

II. Investigators should contact HREP for guidance prior to contacting the NIH issuing authority for guidance on submitting an amended Certificate application, as is required prior to modifying a research project's scope, direction or primary personnel.

III. The condition(s), if any, under which voluntary disclosures will be made must be explicitly stated in the informed consent document so that a research subject's decision to participate is predicated upon their fully informed acceptance of this privacy limitation.

IV. Research subjects recruited prior to a Certificate's issuance should be informed of their newly-afforded privacy protections by providing them with Certificate-related information by way of a revised informed consent document, newsletter, et cetera. If previously recruited research subjects cannot be practicably contacted, the principal investigator should contact the NIH issuing authority and HREP for advice.

V. When an informal request (e.g., telephone call, email) is received for identifying information about research subjects who participated in Certificate-protected research:

A. The requester should be directed to the principal investigator.

B. The principal investigator should notify HREP, the Department's Office of Legal & Regulatory Affairs and the issuing NIH Certificate Coordinator of the request.

C. The principal investigator should explain to the requester that the research is protected by a Certificate and therefore identifying information cannot be disclosed; provide a copy of the Certificate upon request.

VI. When a formal request (i.e., Open Public Records Act, subpoena or congressional oversight of DHHS-funded research) is made to compel the disclosure of identifying information obtained about research subjects who participated in Certificate-protected research:

A. The requester should be referred to the Principal Investigator.

B. The principal investigator should immediately notify HREP, the Department's Office of Legal & Regulatory Affairs and the issuing NIH Certificate Coordinator of the request.

C. The principal investigator should provide the requester with a timely written response stating the research is protected by a Certificate and therefore the requested identifying information cannot be provided; the requester should be provided with a description of any non-identifying information that can be provided. The response should include a copy of the Certificate and current IRB approval letter. HREP should be copied on all correspondence.

VII. HREP strongly recommends maintaining a log of all requests, to include: i) the requester's name and contact information, ii) a description of the requested information (refer to human subjects only by their random unique ID), iii) the reason for the request, iv) a description of the conversation or correspondence, v) the date and time of the request and all follow-up conversations or correspondence and vi) the outcome.

VIII. Disclosing a research subject's identifying information in violation of the ethical obligations or regulatory requirements imposed by a Certificate or informed consent document would likely constitute: i) *serious noncompliance* with the Department's Federalwide Assurance, requiring referral of the violation to the U.S. Department of Health and Human Services (45 CFR 46.103(b)(5)), ii) *serious noncompliance* with the terms and conditions of the IRB's approval, potentially resulting in suspension or termination of the project or the investigator's removal from the project and iii) a breach of the investigator's Memorandum of Agreement for the Ethical Conduct of Research, potential consequences of which include the project's suspension or termination, the investigator being prohibited from conducting future research under the Department's auspices, or further administrative or legal action that could include referral to the New Jersey Office of the Attorney General.

HREP is available to provide training and specific guidance on Federal Certificates of Confidentiality, as well as feedback on draft responses to formal requests for identifying information about research subjects.

C: David Perlman, Ph.D.

Version History
Current Version: v1, Issued 11 July 2006
Previous Version(s): None